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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/144,838	08/31/98	SIANI M	GRFN-020/01U

HM22/0830

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EXAMINER	
WESSENDORF, T	
ART UNIT	**PAPER NUMBER**
1627	18

DATE MAILED: 08/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/144,838	Slani et al
Examiner	**Group Art Unit**
T. Wessendorf	1627

☒ Responsive to communication(s) filed on 7/17/00

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-51 is/are pending in the applicat

Of the above, claim(s) 1-27 and 37-51 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 28-36 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4, 8, 9

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Applicants' election of Group II, claims 28-36 in Paper No. 13 is acknowledged. Also, the election of species, native chemical ligation in Paper No. 15 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-27 and 37-51 are withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

The abstract of the disclosure is objected to because of the used of phraseology often used in patent claims e.g., "comprising". Correction is required. See MPEP § 608.01(b).

The specification is objected to because of the following reasons:

The U.S. Serial No.for the application recited at page 19, lines 28-29 should be provided instead of the Attorney's docket No. Also, the Serial No. of the copending provisional application U.S. Serial No. 06/079,957 at page 30, line 10, is incorrect.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The use of the relative terms, "first" and "second" provides for ambiguity as the standard by which said relative terms are based or measured is unclear.

2. Claim 30 is unclear as to the recitation that the "parent protein molecules are of the same family of protein molecules" .

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by anyone of Canne (J. Am. Soc.)(I) or Dawson et al (science).or Clark Lewis(Biochemistry (I) or the Journal of Biological Chemistry) or Gaerner et al (Bioconjugate Chem.) Or Schnolzer et al (Science).

Canne discloses a method of producing a protein by reacting via thiol exchange a N-terminal peptide segment (oxyethanethiol) peptide with a C terminal segment, thioester and to produce a ligation product 3 (the cross-over protein as claimed) as shown at Scheme 1, page 5892. The different model of ligation of specific peptides are further disclosed by Canne at e.g., page 5892, col. 2 (model ligation #1) up to page 5894, model ligation #5. Therefore the ligation products of the specific peptides are fully met by the broadly cross-over protein having no specific limitation as to the proteins being cross-over.

Dawson teaches ligating two oligopeptides , one oligopeptide having a C-terminal thioester and the other oligopeptide having an N-terminal cys residue, in the presence of a thiol. Spontaneous rearrangement results in the formation of an amide

bond. The oligopeptides are prepared by solid phase synthesis and conversion of the C-terminal thiol. See e.g., page 777, col. 1 and Fig. 1, page 778, footnote 2.

Clark Lewis teaches ligating two oligopeptides , one oligopeptide, Interleukin -8 and the other Neutrophil activating peptide by chemoselectively ligating these two components. See e.g., the abstract at page 3128.

Clark Lewis(II) basically discloses the same chemoselective ligation of two peptides such as IL-8 with CXC chemokine hybrids. See e.g. , page 16075, the abstract. Likewise, Gaerner at e.g., page 333, the abstract. Schnolzer at e.g., page 222 up to page 224.

Claims 32-34 and 36 rejected under 35 U.S.C. 102(b) as being anticipated by Cwirla et al (PNAS).

Cwirla discloses a method of ligating a protein (cross-over as claimed by applicants) of the N-terminus of the pIII of fd phage to which a library of different peptides have been expressed.. See e.g., the abstract at e.g., page 6378. Therefore, the claimed method reciting the broad steps of chemical ligation of the broadly recited components is fully met by Cwirla.

Claims 28-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Sticht et al (Eur. J. Biochem.) Or Zuckermann et al (J. Med. Chem) .

The claimed invention drawn to a method of producing a cross-over protein by ligating two different proteins at the N and C termini wherein the cross-over protein is a single or a library is fully met by the process of Sticht at e.g.,page 27, col. 1 and "Materials and Methods". See Zuckermann at e.g., page 2678, col. 2 up to page 2680, col. 1.

Claims 28-31 are rejected under 35 U.S.C. 102(a) as being anticipated by Wilken(Gryphon Sciences).

The claimed invention is fully met by the process of Wilken. See the entire presentation article.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982);

In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

Claims 28-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 08/945,997 or over claims of copending application S.N. 099094. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly broad claimed method encompass the specific methods of the '997 application which recites species components of the peptides at the N and C-terminal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 28-31 provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 08/945,997 or 09/0999,094 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application.

See the provisional obviousness double patenting, supra.

This provisional rejection might be overcome either by a showing under 37 CAR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CAR 1.131.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1627.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993)(see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat Ph.D., can be reached on (703) 308-0570. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

T. Wessendorf

Patent Examiner
Art Unit 1627
8/23/00